PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

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PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing *(day/month/year)*	14.05.2004
Applicant's or agent's file reference: JNR/PG4886B	**IMPORTANT NOTIFICATION**

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/EP 03/08149	23.07.2003	25.07.2002

Applicant
GLAXO GROUP LIMITED et Al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international preliminary examining authority:
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PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JNR/PG4886B	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP 03/08149	International filing date *(day/month/year)* 23.07.2003	Priority date *(day/month/year)* 25.07.2002
International Patent Classification (IPC) or both national classification and IPC A61M15/00		
Applicant GLAXO GROUP LIMITED et Al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
27.01.2004	14.05.2004
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Kroeders, M Telephone No. +31 70 340-1967

Form PCT/IPEA/409 (Cover Sheet) (January 2004)

Express Mail Label No.
EV332145282US

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP 03/08149

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-41 as originally filed

Claims, Numbers

1-37 as originally filed

Drawings, Sheets

1/9-9/9 as originally filed

2. With regard to the **language,** all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 37

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 37

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	8-10, 12, 13, 15
	No:	Claims	1-7, 11, 14, 16-36
Inventive step (IS)	Yes:	Claims	-
	No:	Claims	1-36
Industrial applicability (IA)	Yes:	Claims	1-36
	No:	Claims	-

2. Citations and explanations

   see separate sheet

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Re Item III
Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

Claim 37 was not searched in view of Article 17(2)(a)(i) PCT and Rule 39.1(iv) PCT and therefore no substantive examination can be performed.
Moreover, claim 37 relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated on the subject-matter of this claim (Article 34(4)(a)(i) PCT).

Re Item V
Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The subject-matter of claim 1 does not meet the requirements of Article 33(2) PCT.

The document WO-A-0204055 discloses (the references in parentheses applying to this document):

a medicament dispenser (2) for use in the delivery of a combination medicament product to a patient, the dispenser (2) comprising:
a first medicament container (14) for containing a first medicament component;
a first release means (20) for releasing the contents of said first medicament container (14);
at least one further medicament container (16) for containing at least one further medicament component; and
at least one further release means (20) for releasing the contents of each said at least one further medicament container (16);
wherein the first medicament component is kept separate from the at least one further medicament component until the point of release thereof for delivery in combination, and wherein the dispenser (2) additionally comprises
an electronic control system (51) for controlling the release of contents from the first and at least one further medicament container (14, 16)

The subject-matter of claim 1 is therefore not new (Article 33(2) PCT).
This objection also holds true in view of documents US-B1-6234167 (column 3, line 46

to column 9, line 51), US-A-5778873 (column 3, line 7 to column 11, line 17).

The device of claim 1 is industrially manufacturable and, as such, meets the requirements of Article 33(4) PCT. Claims 2 to 36 are all eventually dependent from claim 1, and therefore also meet the requirements of Article 33(4) PCT.

However, dependent claims 2 to 36 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:

The features of claims 2 to 7, 11, 14 and 16 to 36 all relate to normal design features (generic features of the electronic control system, coupling of the release means, breath actuated activation, medicaments to be delivered) that are already known and disclosed in the prior art documents see e.g. WO-A-0204055 (page 1, line 11 to page 6, line 25), US-B1-6234167 (column 3, line 46 to column 9, line 51) or US-A-5778873 (column 3, line 7 to column 11, line 17). Therefore, these claims do not meet the requirements of Article 33(2) PCT.

The remaining claims (8 to 10, 12, 13 and 15) relate to a diagnostic system, and communication means for transmitting/linking the dispenser data to a different location. A similar system is already known from document WO-A-0124690 (page 2, line 20 to page 11, line 9). Including this system in a dispenser for delivering two medicaments in combination does not involve an inventive step (Article 33(3) PCT).

The following document is cited under Rule 70.10 PCT, as it constitutes prior art for the purposes of Article 33(2) PCT for claims 1 - 15 and 19 - 36.

Certain published documents:

Application No Patent No	Publication date *(day/month/year)*	Filing date *(day/month/year)*	Priority date *(valid claim)* *(day/month/year)*
WO-A-03061743 31	31-07-2003	22-01-2003	25-01-2002